

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.
11808-045-999
(CAM: 120024-999045)

APPLICATION NO.
10/563,418

APPLICANT
Jungles et al.

FILING DATE
July 24, 2007

ART UNIT
1618

U.S. PATENT DOCUMENTS

*Examiner Initials	Document Number	Date yyyy-mm-dd	Name of Patentee or Applicant of Cited Document
	A01 2,568,685	1951-09-18	Petering et al.
	A02 4,252,822	1981-02-24	Berry et al.
	A03 4,943,575	1990-07-24	Cremer
	A04 5,043,446	1991-08-27	Kikuchi et al.
	A05 5,198,469	1993-03-30	Sakata
	A06 5,418,192	1995-05-23	Borden et al.
	A07 5,439,799	1995-08-08	Rautenberg et al.
	A08 5,449,688	1995-09-12	Wahl et al.
	A09 5,468,630	1995-11-21	Billiar et al.
	A10 5,468,772	1995-11-21	Xu et al.
	A11 5,502,050	1996-03-26	Gross
	A12 5,554,647	1996-09-10	Perricone
	A13 5,606,020	1997-02-25	Watanabe et al.
	A14 5,643,586	1997-07-01	Perricone
	A15 5,658,565	1997-08-19	Billiar et al.
	A16 5,744,340	1998-04-28	Fossetta et al.
	A17 5,763,392	1998-06-09	Hansen et al.
	A18 5,830,461	1998-11-03	Billiar et al.
	A19 5,846,775	1998-12-08	Hillman et al.
	A20 5,856,158	1999-01-05	Rosazza et al.
	A21 5,874,433	1999-02-23	Gross
	A22 5,877,176	1999-03-02	Gross
	A23 5,879,690	1999-03-09	Perricone
	A24 5,880,124	1999-03-09	Gross
	A25 5,882,908	1999-03-16	Billiar et al.
	A26 5,932,208	1999-08-03	Chedid et al.
	A27 6,022,879	2000-02-08	Crow et al.
	A28 6,046,010	2000-04-04	Anderson
	A29 6,103,230	2000-08-15	Billiar et al.
	A30 6,117,872	2000-09-12	Maxwell et al.

SDI-21115v2

EXAMINER

/James Rogers/

DATE CONSIDERED

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* Examiner Initials		Document Number	Date yyyy-mm-dd	Name of Patentee or Applicant of Cited Document	
	A31	6,153,615	2000-11-28	Gross	
	A32	6,162,914	2000-12-19	Toderi et al.	
	A33	6,177,280	2001-01-23	Yan et al.	
	A34	6,180,597	2001-01-30	Liao	
	A35	6,200,758	2001-03-13	Richardson	
	A36	6,245,776	2001-06-12	Skwierczynski et al.	
	A37	6,251,953	2001-06-26	Baranowitz	
	A38	6,288,535	2001-09-11	Chass	
	A39	6,319,905	2001-11-20	Mandel et al.	
	A40	6,346,519	2002-02-12	Petrus	
	A41	6,423,751	2002-07-23	Liao	
	A42	6,428,990	2002-08-06	Mukerji et al.	
	A43	6,486,168	2002-11-26	Skwierczynski et al.	
	A44	6,500,857	2002-12-31	Perricone	
	A45	6,537,992	2003-03-25	Parker	
	A46	6,562,969	2003-05-13	Robertus et al.	
	A47	6,576,105	2003-06-10	Ma	
	A48	6,617,359	2003-09-09	Wohlfiart et al.	
	A49	6,649,345	2003-11-18	Richardson	
	A50	6,656,925	2003-12-02	Petrus	
	A51	6,660,831	2003-12-09	Fallon	
	A52	6,689,385	2004-02-10	Richardson et al.	
	A53	6,693,094	2004-02-17	Pearson et al.	
	A54	6,696,480	2004-02-24	Liao	
	A55	6,706,728	2004-03-16	Hedenstrom et al.	
	A56	6,749,875	2004-06-15	Selleck	
	A57	6,787,178	2004-08-31	Gross et al.	
	A58	6,995,158	2006-02-07	Rabelink et al.	
	A59	7,566,462	2009-07-28	Jungles et al.	
	A60	2002/0037284	2002-03-28	Fallon	

SDI-21115v2

EXAMINER

/James Rogers/

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	A61 2002/0052374	2002-05-02	Rabelink et al.
	A62 2002/0058674	2002-05-16	Hedenstrom et al.
	A63 2002/0061862	2002-05-23	Billiar et al.
	A64 2002/0082261	2002-06-27	Kashiwagi et al.
	A65 2002/0119952	2002-08-29	Petrus
	A66 2002/0155445	2002-10-24	Jarvik
	A67 2003/0004125	2003-01-02	Hirst et al.
	A68 2003/0045543	2003-03-06	Hedenstrom et al.
	A69 2003/0077335	2003-04-24	Richardson et al.
	A70 2003/0078231	2003-04-24	Wilburn
	A71 2003/0124524	2003-07-03	Kornman et al.
	A72 2003/0212135	2003-11-13	Gross et al.
	A73 2003/0216400	2003-11-20	Rabelink et al.
	A74 2003/0232835	2003-12-18	Ishihara et al.
	A75 2004/0002129	2004-01-01	Hennies et al.
	A76 2004/0014167	2004-01-22	Yabuta et al.
	A77 2004/0034030	2004-04-22	Richardson et al.
	A78 2004/0077859	2004-06-17	Waer et al.
	A79 2004/0115182	2004-06-17	Fallon
	A80 2004/0162269	2004-08-19	Petrus
	A81 2005/0137141	2005-06-23	Hilfinger
	A82 2005/0239807	2005-10-27	Stamler et al.
	A83 2006/0040946	2006-02-23	Oppenheimer et al.
	A84 2006/0194808	2006-08-31	Richardson et al.
	A85 2006/0211701	2006-09-21	Muntau-Heger et al.
	A86 2007/0167353	2007-07-19	Hilfinger et al.
	A87 2007/0270581	2007-11-22	Jungles et al.
	A88 2008/0075666	2008-03-27	Dudley et al.
	A89 2008/0090832	2008-04-17	Oppenheimer et al.
	A90 2008/0146577	2008-06-19	Matalon et al.

SDI-21115v2

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1618**U.S. PATENT DOCUMENTS**

*Examiner Initials	Document Number	Date yyyy-mm-dd	Name of Patentee or Applicant of Cited Document
A91	2008/0213239	2008-09-04	Morris

FOREIGN PATENT DOCUMENTS

*Examiner Initials	Foreign Patent Document Country Code, Number, Kind Code (if known)	Date yyyy-mm-dd	Name of Patentee or Applicant of Cited Document	T
	B01 EP 0108890	1984-05-23	Wellcome Found. et al.	
	B02 EP 0209689	1987-01-28	Suntory Ltd.	
	B03 EP 0318926	1988-11-29	Vitamin Kenkyusho KK	
	B04 EP 0349204	1989-06-23	Bend Res Inc.	
	B05 EP 0488078	1992-06-03	Milupa AG	
	B06 EP 0722731	1996-07-24	Suntory Ltd.	
	B07 EP 0908182	1999-04-14	Suntory Ltd	
	B08 EP 0983765	2000-03-08	Suntory Ltd	
	B09 EP 1314782	2003-05-28	Suntory Ltd	
	B10 EP 1964566	2005-12-22	Asubio Pharma Co., Ltd.	
	B11 JP 05009065	1984-05-11	Suntory Ltd	
	B12 JP 60204786	1985-10-16	Nagoya Daigaku Gakucho et al.	
	B13 JP 63063613	1988-03-22	Kanegafuchi Chemical Ind. et al.	
	B14 WO 1995/013075	1995-05-18	Cell Therapeutics Inc. et al.	
	B15 WO 1995/028377	1995-10-26	Abbott Lab. et al.	
	B16 WO 1997/044029	1997-11-27	Eli Lilly Co. et al.	
	B17 WO 1998/008516	1998-03-05	Suntory Ltd et al.	
	B18 WO 1999/043325	1999-09-02	Suntory Ltd et al.	
	B19 WO 1999/047153	1999-09-23	Brigham & Womens Hospital et al.	
	B20 WO 2000/003746	2000-01-27	Brigham & Womens Hospital et al.	
	B21 WO 2000/037653	2000-06-29	Board of Regents, The Univ. of Texas	
	B22 WO 2000/056403	2000-09-28	Brigham & Womens Hospital et al.	
	B23 WO 2001/056551	2001-08-09	Univ. of Zurich	
	B24 WO 2002/017898	2002-03-07	Sacks	

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	B25	WO 2003/072096	2003-09-04	Merck Eprova AG	
	B26	WO 2003/077837	2003-09-25	Boyce Thompson Inst. For Plant Res.	
	B27	WO 2003/080063	2003-10-02	Daiichi Sankyo Pharma Co. Ltd.	
	B28	WO 2003/084388	2003-10-16	Becton, Dickinson and Co.	
	B29	WO 2004/002404	2004-01-08	Nastech Pharm. Co. Inc.	
	B30	WO 2004/016764	2004-02-26	Schering Aktiengesellschaft	
	B31	WO 2004/017955	2004-03-04	Vasopharm Biotech. GMBH	
	B32	WO 2004/041169	2004-05-21	Bach Pharma, Inc.	
	B33	WO 2004/044602	2004-05-24	Nederlandse Organisatie Voor Toegepast-Natuurwetenschappelijk Onderzoek TNO	
	B34	WO 2004/058268	2004-07-15	Orphanetics Pharma Entwicklungs GMBH	
	B35	WO 2006/063215	2006-06-15	BioMarin Pharmaceutical Inc.	
	B36	WO 2006/112495	2006-10-26	Shiratori Pharmaceutical Co., Ltd.	
	B37	WO 2006/118322	2006-11-09	Shiratori Pharmaceutical Co., Ltd.	
	B38	WO 2007/007291	2007-01-18	L'Oreal	
	B39	WO 2007/067570	2007-06-14	BioMarin Pharmaceutical Inc.	

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	AQEEL ET AL., "Response of 6-pyruvoyl-tetrahydrobiopterin synthase deficiency to tetrahydrobiopterin," <i>J. Child Neurology</i> , 1992 , 7, S26-S30.	
	C02	ARNOLD, Phenylketonuria, eMedicine from webMD, 06-05-06, http://www.emedline.com/PED/topic1787.htm pages 1-8.	
	C03	BELANGER-QUINTANA ET AL., "Spanish BH4-responsive phenylalanine hydroxylase deficient patients: Evolution of seven patients on long-term treatment with tetrahydrobiopterin," <i>Mol. Genet. Metab.</i> 2005 , 86, S61-S66.	
	C04	BIJELAKOVIC ET AL., "Biochemical functions and clinical importance of unconjugated pteridines," <i>Medicine and Biology</i> 2004 , 11, 49-54.	
	C05	BLAU ET AL., 34th EMG Meeting, Zurich, CH, May 31-June 2, 2002, proceedings published October 2002 .	
	C06	BLAU ET AL., "Disorders of phenylalanine and tetrahydrobiopterin metabolism" in <i>Physician's Guide to the Laboratory Diagnosis of Metabolic Diseases</i> , 2nd ed., Blau et al., eds., Heidelberg, Springer-Verlag, 2003 , pages 89-106.	

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C07	BLAU ET AL., "Optimizing the use of sapropterin (BH4) in the management of phenylketonuria," <i>Mol. Genet. Metab.</i> 2009 , <i>96</i> , 158-163.	
C08	BONAFE ET AL., "Treatable neurotransmitter deficiency in mild phenylketonuria," <i>Neurology</i> 2001 , <i>57</i> , 908-911.	
C09	CERONE ET AL., "Long-term follow-up of a patient with mild tetrahydrobiopterin-responsive phenylketonuria," <i>Mol. Genet. Metab.</i> 2004 , <i>81</i> , 137-139.	
C10	CHOI ET AL., "Tetrahydrobiopterin is released from and causes preferential death of catecholaminergic cells by oxidative stress," <i>Mol. Pharm.</i> 2000 , <i>58</i> , 633-640.	
C11	COSENTINO ET AL., "Tetrahydrobiopterin and dysfunction of endothelial nitric oxide synthase in coronary arteries," <i>Circulation</i> 1995 , <i>91</i> , 139-144.	
C12	CURTUS ET AL., "Therapeutic efficacy of tetrahydrobiopterin in Parkinson's disease," <i>Adv. Neurol.</i> 1984 , <i>40</i> , 463-466.	
C13	CURTUS ET AL., "Successful treatment of depression with tetrahydrobiopterin," <i>Lancet</i> 1983 , <i>1</i> , 657-658.	
C14	DANKS ET AL., "Variant forms of phenylketonuria," <i>Lancet</i> 1976 , <i>1</i> , 1236-1237.	
C15	DE VRIESE ET AL., "Endothelial dysfunction in diabetes," <i>Br. J. Pharm.</i> 2000 , <i>130</i> , 963-974.	
C16	DE VRIESE ET AL., "Mild to moderate hyperhomocysteinaemia in cardiovascular disease," <i>Acta Cardiol.</i> 1998 , <i>53</i> , 337-344.	
C17	DEFILY, "Control of microvascular resistance in physiological conditions and reperfusion," <i>J. Mol. Cell. Cardiol.</i> 1998 , <i>30</i> , 2547-2554.	
C18	DHONDT ET AL., "Atypical cases of phenylketonuria," <i>Eur. J. Pediatr.</i> 1987 , <i>146</i> , A38-A43.	
C19	DHONDT ET AL., "Diagnosis of variants of hyperphenylalaninemia by determination of pterins in urine," <i>Clin. Chim. Acta</i> 1981 , <i>110</i> , 205-214.	
C20	DHONDT ET AL., "Pterin metabolism in normal subjects and hyperphenylalaninaemic patients," <i>J. Inher. Metab. Dis.</i> 1981 , <i>4</i> , 47-48.	
C21	Disorder index of the National Institute of Neurological Disorders and Stroke, http://www.ninds.nih.gov/disorders/disorder_index.htm?css=print (inactive URL)	
C22	DISSING ET AL., "Tetrahydrobiopterin and Parkinson's disease," <i>Acta Neurol. Scand.</i> 1989 , <i>79</i> , 493-499.	
C23	DUDESEK ET AL., "Molecular analysis and long-term follow-up of patients with different forms of 6-pyruvoyl-tetrahydropterin synthase deficiency," <i>Eur. J. Pediatr.</i> 2001 , <i>160</i> , 267-276.	
C24	ELLIS, "The general concept of molecular chaperones," <i>Philos. Trans. R. Soc. Lond. B. Biol. Sci.</i> 1993 , <i>339</i> , 257-261.	
C25	ENDRES ET AL., "Atypical phenylketonuria due to biopterin deficiency," <i>Helv. Paediat. Acta</i> 1982 , <i>37</i> , 489-498.	
C26	ERLANDSEN ET AL., "A structural hypothesis for BH4 responsiveness in patients with mild forms of hyperphenylalaninaemia and phenylketonuria," <i>J. Inher. Metab.</i> 2001 , <i>24</i> , 213-230.	
C27	FERRARIS ET AL., "Essai de dépistage indirect des déficits en tetrahydrobiopterine," <i>Pediatr. Acta</i> 1987 , <i>42</i> , 549-555.	
C28	FIEGE ET AL., "Plasma tetrahydrobiopterin and its pharmacokinetic following oral administration," <i>Mol. Genet. Metab.</i> 2004 , <i>81</i> , 45-51.	
C29	FURRER ET AL., "Trennung de diastereomeren (6R)- und (6S)-5,6,7,8-tetrahydro-L-biopterin," <i>Helv. Chim. Acta</i> 1979 , <i>62</i> , 2577-2580.	
C30	GALLEY ET AL., "Circulating tetrahydrobiopterin concentrations in patients with septic shock," <i>Brit. J. Anaesthesia</i> 2001 , <i>86</i> , 578-580.	

SDI-21115v2

EXAMINER

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C31	GIUGLIANI ET AL., "Successful therapy of hyperphenylalaninemia due to defective tetrahydrobiopterin metabolism in two siblings," <i>Rev. Brasil. Genet.</i> IX 1986 , 4, 685-692.	
C32	GUTTIER ET AL., "Hyperphenylalaninemia: Diagnosis and classification of the various types of phenylalanine hydroxylase deficiency in childhood," <i>Acta Paediatrica Scandinavica Supplement</i> 1980 , 280.	
C33	HAJEK ET AL., "Proton in vivo spectroscopy of patients with hyperphenylalaninaemia," <i>Neuropediatrics</i> 1993 , 24, 111-112.	
C34	HEITZER ET AL., "Tetrahydrobiopterin improves endothelium-dependent vasodilation by increasing nitric oxide activity in patients with Type II diabetes mellitus," <i>Circ. Res.</i> 2000 , 43, 1435-1438.	
C35	HENNERMANN ET AL., "Partial and total tetrahydrobiopterin-responsiveness in classical and mild phenylketonuria (PKU)," <i>J. Inher. Metab. Dis.</i> 2002 , 25(Suppl. 1), 21.	
C36	HENNERMANN ET AL., "Long-term treatment with tetrahydrobiopterin increases phenylalanine tolerance in children with severe phenotype of phenylketonuria," <i>Mol. Genet. Metab.</i> 2005 , 86, S86-S90.	
C37	IISIA ET AL., "Hyperphenylalaninemia," <i>Metab.</i> 1967 , 16, 99-101.	
C38	IJUEETHER ET AL., "Individual carboxylic ester hydrolases of the developing cerebellum, influence of experimental hyperphenylalaninaemia," <i>Cell. Mol. Biol.</i> 1982 , 28, 313-317.	
C39	HYLAND ET AL., "Matters arising," <i>J. Neurol. Neurosurg. Psychiatry</i> 1987 , 50, 242-243.	
C40	KATUSIC, "Vascular endothelial dysfunction: does tetrahydrobiopterin play a role?" <i>Am. J. Physiol. Heart Circ. Physiol.</i> 2001 , 281, H981-H986.	
C41	KAUFMAN, "Hepatic phenylalanine hydroxylase and PKU," in <i>Brian mechanisms in mental retardation: Proceeding of a conference in the series on mental retardation sponsored by the National Institute of Child Health and Human Development mental Retardation Research Centers Series</i> , NY, Academic Press, 1975 , pages 445-458.	
C42	KAUFMAN, "Phenylketonuria and its variants," <i>Ann. Clin. Lab. Sci.</i> 1977 , 7, 178-185.	
C43	KAUFMAN, "Phenylketonuria due to a deficiency of dihydropteridine reductase," <i>N. Engl. J. Med.</i> 1975 , 293, 785-790.	
C44	KAUFMAN, "Unsolved problems in diagnosis and therapy of hyperphenylalaninemia caused by defects in tetrahydrobiopterin metabolism," <i>J. Pediatr.</i> 1986 , 109, 572-578.	
C45	KHRIPACK ET AL., <i>Khimiya Geterotsiklicheskikh Soedinenii</i> 1975 , 6, 844-846.	
C46	KOCH ET AL., "Large neutral amino acid therapy and phenylketonuria: A promising approach to treatment," <i>Mol. Genet. Metab.</i> 2003 , 79, 110-113.	
C47	KREDAN ET AL., "Homocysteine-induced endothelial superoxide anion production is inhibited by tetrahydrobiopterin and folate," <i>Eur. Heart J.</i> 1999 , 20, 41.	
C48	KURE ET AL., "Tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency," <i>J. Pediatr.</i> 1999 , 135, 375-378.	
C49	KUVAN TM [sapropterin dihydrochloride (BH4)] Tablets Product Information, 2007 , pages 1-17.	
C50	LAFFRANCHI ET AL., "Tetrahydrobiopterin synthesis precedes nitric oxide-dependent inhibition of insulin secretion in INS-1 rat pancreatic beta-cells," <i>Biochem. Biophys. Res. Commun.</i> 1997 , 233, 66-70.	
C51	LAMBRUSCHINI ET AL., "Clinical and nutritional evaluation of phenylketonuric patients on tetrahydrobiopterin monotherapy," <i>Mol. Genet. Metab.</i> 2005 , 86, S54-S60.	
C52	LANG ET AL., "Homocysteine-induced endothelial superoxide anion production is inhibited by tetrahydrobiopterin and folate," <i>Circ.</i> 1999 , 100, 411.	
C53	LASSKER ET AL., "Tetrahydrobiopterin responsiveness in phenylketonuria," <i>J. Inher. Metab. Dis.</i> 2002 , 25, 65-70.	

SDI-21115v2

EXAMINER

/James Rogers/

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C54	LEEMING ET AL., "Relationship between plasma and red cell bipterins in acute and chronic hyperphenylalaninemia," <i>J. Inher. Metab. Dis.</i> 1990 , <i>13</i> , 883-887.	
C55	LEVY ET AL., "Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin 6R-BH4) for reduction of phenylalanine concentration in patients with phenylketonuria: A phase III randomised placebo-controlled study," <i>Lancet</i> 2007 , <i>370</i> , 504-510.	
C56	LEVY ET AL., "Recommendations for evaluation of responsiveness to tetrahydrobiopterin (BH4) in phenylketonuria and its use in treatment," <i>Mol. Genet. Metab.</i> 2007 , <i>92</i> , 287-291.	
C57	LINDER ET AL., "Tetrahydrobiopterin responsiveness in phenylketonuria differs between patients with the same genotype," <i>Mol. Genet. Metab.</i> 2001 , <i>73</i> , 104-106.	
C58	LUCKE ET AL., "BH4-sensitive hyperphenylalaninemia: New case and review of literature," <i>Pediatric Neurology</i> 2003 , <i>28</i> , 228-230.	
C59	LUCOCK ET AL., "The impact of phenylketonuria on folate metabolism," <i>Mol. Genet. Metab.</i> 2002 , <i>76</i> , 305-312.	
C60	MABRY ET AL., "Phenylketonuria: Contemporary screening and diagnosis," <i>Ann. Clin. Lab. Sci.</i> 1990 , <i>20</i> , 392-397.	
C61	MAIER ET AL., "Tetrahydrobiopterin improves endothelial function in patients with coronary artery disease," <i>J. Cardiovasc. Pharmacol.</i> 2000 , <i>35</i> , 173-178.	
C62	MALLOLAS ET AL., "Mutational spectrum of phenylalanine hydroxylase deficiency in the population resident of Catalonia: Genotype-phenotype correlation," <i>Hum. Genet.</i> 1999 , <i>103</i> , 468-473.	
C63	MATALON ET AL., "Phenylketonuria: Screening, treatment and maternal PKU," <i>Clin. Biochem.</i> 1991 , <i>24</i> , 337-342.	
C64	MATSUBARA ET AL., "Improved diagnosis of classical vs. Atypical phenylketonuria by liquid chromatography," <i>Clin. Chem.</i> 1984 , <i>30</i> , 278-280.	
C65	MCCAMAN ET AL., "Fluorimetric method for the determination of phenylalanine in serum," <i>J. Lab. Clin. Med.</i> 1962 , <i>59</i> , 885-890.	
C66	MEININGER ET AL., "Impaired nitric oxide production in coronary endothelial cells of the spontaneously diabetic BB rat is due to tetrahydrobiopterin deficiency," <i>Biochem. J.</i> 2000 , <i>349</i> , 353-356.	
C67	MILSTEIN, "Interconversion of 6- and 7-substituted tetrahydropterins via enzyme-generated 4a-hydroxytetrahydropterin intermediates," <i>Meth. Enzymol.</i> 1997 , <i>281</i> , 116-123.	
C68	MISSIOU-TSAGARAKI ET AL., "Phenylketonuria in Greece: 12 Years' experience," <i>J. Mental Deficiency Res.</i> 1988 , <i>32</i> , 271-287.	
C69	MITCHELL ET AL., "Tetrahydrobiopterin-responsive phenylketonuria: the New South Wales experience," <i>Mol. Genet. Metab.</i> 2005 , <i>86</i> , S81-S85.	
C70	MOHYUDDIN ET AL., "Screening for bipterin defects among hyperphenylalaninemic patients: Report of a Canadian program after 3 years," <i>Chem. Biol. Pteridines</i> 1986 , 243-246.	
C71	MUNTAU ET AL., "Tetrahydrobiopterin as an alternative treatment for Mills phenylketonuria," <i>N. Engl. J. Med.</i> 2002 , <i>347</i> , 2122-2132.	
C72	NIEDERWIESER ET AL., "Atypical phenylketonuria with defective bipterin metabolism. Monotherapy with tetrahydrobiopterin or sepiapterin, screening and study of biosynthesis in man," <i>Eur. J. Pediatr.</i> 1982 , <i>138</i> , 110-112.	
C73	NIEDERWIESER ET AL., "Peripheral tetrahydrobiopterin deficiency with hyperphenylalaninemia due to incomplete 6-pyruvoyl tetrahydropterin synthase deficiency or heterozygosity," <i>Eur. J. Pediatr.</i> 1987 , <i>146</i> , 228-232.	
C74	NIXON ET AL., "Neopterin and bipterin levels in patients with atypical forms of phenylketonuria," <i>J. Neurochem.</i> 1980 , <i>35</i> , 898-904.	
C75	NYSTROM ET AL., "Tetrahydrobiopterin increases insulin sensitivity in patients with type 2 diabetes and	

SDI-21115v2

EXAMINER

/James Rogers/

DATE CONSIDERED

04/22/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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 ATTY. DOCKET NO.
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(CAM: 120024-999045)

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NON PATENT LITERATURE DOCUMENTS

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	coronary heart disease," <i>Am. J. Physiol. Endocrinol. Metab.</i> 2004 , 287, E919-E925.	
C76	O'BRIEN ET AL., <i>US Pharmacist</i> 1997 , 22, 62-75.	
C77	OGAWA ET AL., "A case of 6-pyruvoyl-tetrahydropterin synthase deficiency demonstrates a more significant correlation to L-dopa dosage with serum prolactin levels than CSF homovanillic acid levels," <i>Brain Develop.</i> 2008 , 30, 82-85.	
C78	PARKER, "Diseases of phenylalanine metabolism," <i>Western J. Med.</i> 1979 , 131, 285-297.	
C79	PATTERSON ET AL., "The synthesis of a pteridine required for the growth of crithidia fasciculata," <i>J. Am. Chem. Soc.</i> 1956 , 78, 5868-5871.	
C80	PhenylAde Amino Acid Bars Brochure, November 2002.	
C81	PhenylAde Amino Acid Blends Brochure, May 2002.	
C82	PIEPER, "Acute amelioration of diabetic endothelial dysfunction with a derivative of the nitric oxide synthase cofactor, tetrahydrobiopterin," <i>J. Cardiovasc. Pharmacol.</i> 1997 , 29, 8-15.	
C83	PONZONE ET AL., "Catalytic activity of tetrahydrobiopterin in dihydropteridine reductase deficiency and indications for treatment," <i>Pediatric Res.</i> 1993 , 33, 125-128.	
C84	PONZONE ET AL., "Hyperphenylalaninemia and pterin metabolism in serum and erythrocytes," <i>Clin. Chem. Acta</i> 1993 , 216, 63-71.	
C85	PONZONE ET AL., "Differential diagnosis of hyperphenylalaninemia by a combined phenylalanine-tetrahydrobiopterin loading test," <i>Eur. J. Pediatr.</i> 1993 , 152, 655-661.	
C86	PONZONE ET AL., "Tetrahydrobiopterin loading test in hyperphenylalaninemia," <i>Pediatric Res.</i> 1991 , 30, 435-438.	
C87	PRIMROSE, "Phenylketonuria with normal intelligence," <i>J. Ment. Deic. Res.</i> 1983 , 27, 239-246.	
C88	RABINOFF, "Possible uses of urinary neopterin and biopterin measurement," <i>Med. Hypotheses</i> 1989 , 29, 241-243.	
C89	REY ET AL., "Kinetics of phenylalanine disappearance after intravenous load in phenylketonuria and its genetic variants," <i>Pediatr. Res.</i> 1979 , 13, 21-25.	
C90	ROTH, "Newborn metabolic screening: A search for "nature experiments,"" <i>Curr. Concepts Diagnosis</i> 1986 , 79, 47-54.	
C91	SCHAUB ET AL., "Tetrahydrobiopterin therapy of atypical phenylketonuria due to defective dihydrobiopterin biosynthesis," <i>Arch. Dis. Child.</i> 1978 , 53, 674-676.	
C92	SCHIRCKS LABORATORIES, Tetrahydrobiopterin, Sales restrictions, June 2006, http://www.schircks.com/tablets/tablet_info.htm	
C93	SCHLESINGER ET AL., "Urinary dihydroxanthopterin in the diagnosis of malignant hyperphenylalaninemia and phenylketonuria," <i>Clin. Chim. Acta</i> 1979 , 92, 187-195.	
C94	SCHMIDT ET AL., "The nitric oxide synthase cofactor tetrahydrobiopterine reduces allograft ischemia-reperfusion injury after liver transplantation," <i>J. Thorac. Cardiovasc. Surg.</i> 1999 , 118, 726-732.	
C95	SCHMIDT ET AL., "Single dose oral tetrahydrobiopterin (BH4) leads to a prolonged increase in aortic BH4 levels in ApoE-KO mice," <i>Eur. J. Cardiovasc. Prev. Rehab.</i> 2007 , 193, S4.	
C96	SCHULZE ET AL., "Evaluation of 6-year application of the enzymatic colorimetric phenylalanine assay in the setting of neonatal screening for phenylketonuria," <i>Clin. Chim. Acta</i> 2002 , 317, 27-37.	
C97	SCRIVER ET AL., "Hyperphenylalaninemia: Phenylalanine hydroxylase deficiency," <i>New York: McGraw-Hill</i> , 2001 , pages 1667-1724.	
C98	SCRIVER, "Science, medicine and phenylketonuria," <i>Acta Paediatr.</i> 1994 , 407, 11-18.	

SDI-21115v2

EXAMINER

/James Rogers/

DATE CONSIDERED

04/22/2011

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	C99	SEASHORE, "Tetrahydrobiopterin and dietary restriction in mild phenylketonuria," <i>N. Engl. J. Med.</i> 2002 , 347, 2094-2095.	
	C100	SHARMA ET AL., "Development of a refractory stage in a dog model for phenylketonuria," <i>Res. Commun. Chem. Pathol. Pharmacol.</i> 1981 , 33, 145-153.	
	C101	SHAW ET AL., "Analytical methods in phenylketonuria clinical biochemistry," in Phenylketonuria and some other inborn errors of amino acid metabolism, Bickert et al., Eds., Stuttgart: Georg. Thiem Verlag, 47, 1969 , pages 47-56.	
	C102	SHIMIZU ET AL., "Protective effects of tetrahydrobiopterin against nitric oxide-induced endothelial cell death," <i>Life Sci.</i> 1998 , 63, 1585-1592.	
	C103	SHIMIZU ET AL., "Role of tetrahydrobiopterin in the function of nitric oxide synthase, and its cytoprotective effect," <i>Int. J. Mol. Med.</i> 1998 , 2, 533-540.	
	C104	SHINOZAKI ET AL., "Abnormal biopterin metabolism is a major cause of impaired endothelium-dependent relaxation through nitric oxide/O ₂ -imbalance in insulin-resistant rat aorta," <i>Diabetes</i> 1999 , 48, 2437-2445.	
	C105	SHINOZAKI ET AL., "Oral administration of tetrahydrobiopterin prevents endothelial dysfunction and vascular oxidative stress in the aortas of insulin-resistant rats," <i>Circ. Res.</i> 2000 , 87, 566-573.	
	C106	SHINTAKU ET AL., "Tetrahydrobiopterin, responsive, hyperphenylalaninemia without biopterin deficiency," <i>Pteridines</i> 2000 , 11, 83-84.	
	C107	SHINTAKU ET AL., "Disorders of tetrahydrobiopterin metabolism and their treatment," <i>Curr. Drug Metab.</i> 2002 , 3, 123-131.	
	C108	SHINTAKU ET AL., "Long-term treatment and diagnosis of tetrahydrobiopterin-responsive hyperphenylalaninemia with a mutant phenylalanine hydroxylase gene," <i>Pediatric Res.</i> 2004 , 55, 425-430.	
	C109	SHINTAKU ET AL., "Plasma biopterin levels and tetrahydrobiopterin responsiveness," <i>Mol. Genet. Metab.</i> 2005 , 86, S104-S106.	
	C110	SLAZYK ET AL., "Liquid-chromatographic measurement of biopterin and neopterin in serum and urine," <i>Clin. Chem.</i> 1990 , 36, 1364-1368.	
	C111	SMITH ET AL., "Neurological aspects of biopterin metabolism," <i>Arch. Dis. Child.</i> 1986 , 61, 130-137.	
	C112	SMITH ET AL., "New variant of phenylketonuria with progressive neurological illness unresponsive to phenylalanine restriction," <i>Lancet</i> 1975 , 1, 1108-1111.	
	C113	SPAAPEN ET AL., "Tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency in Dutch neonates," <i>J. Inher. Dis.</i> 2001 , 24, 352-358.	
	C114	SPAAPEN ET AL., "Tetrahydrobiopterin-responsive phenylalanine hydroxylase deficiency, state of the art," <i>Mol. Genet. Metab.</i> 2003 , 78, 93-99.	
	C115	STEINFELD ET AL., "Tetrahydrobiopterin monotherapy for phenylketonuria patients with common mild mutations," <i>Eur. J. Pediatr.</i> 2002 , 161, 403-405.	
	C116	STEINFELD ET AL., "A hypothesis on the biochemical mechanism of BH4-responsiveness in phenylalanine hydroxylase deficiency," <i>Amino Acids</i> 2003 , 25, 63-68.	
	C117	TADA ET AL., "Follow-up study of a nationwide neonatal metabolic screening program in Japan," <i>Eur. J. Pediatr.</i> 1984 , 145, 204-207.	
	C118	TANAKA ET AL., "Hyperphenylalaninemia due to impaired dihydrobiopterin biosynthesis," <i>Eur. J. Pediatr.</i> 1981 , 136, 275-280.	
	C119	TANAKA ET AL., "Early initiation of L-dopa therapy enables stable development of executive function in tetrahydrobiopterin (BH4) deficiency," <i>Develop. Med. Child Neurology</i> 2007 , 49, 372-376.	
	C120	TAYLOR ET AL., "Pteridines. XXXVII. A total synthesis of L-erythro-biopterin and some related 6-(polyhydroxyalkyl)pterins," <i>J. Am. Chem. Soc.</i> 1976 , 98, 2301-2307.	
	C121	THONY ET AL., "Mutations in the pterin-4- α carbinolamine dehydratase (PCBD) gene cause a benign form of hyperphenylalaninemia," <i>Human Genet.</i> 1998 , 103, 162-167.	

SDE-21115v2

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C122	TIEFENBACHER ET AL., "Endothelial dysfunction of coronary resistance arteries is improved by tetrahydrobiopterin in atherosclerosis," <i>Circ.</i> 2000 , <i>102</i> , 2172-2179.	
C123	TREACT ET AL., "Analysis of phenylalanine hydroxylase genotypes and hyperphenylalaninemia phenotypes using L-[1- ¹³ C]phenylalanine oxidation rates in vivo: A pilot study," <i>Pediatr. Res.</i> 1997 , <i>42</i> , 430-435.	
C124	TREFZ ET AL., "Successful treatment of phenylketonuria by tetrahydrobiopterin," <i>Eur. J. Pediatr.</i> 2001 , <i>160</i> , 315.	
C125	TREFZ ET AL., "Potential role of tetrahydrobiopterin in the treatment of maternal phenylketonuria," <i>Pediatrics</i> 2003 , <i>112</i> , 1566-1569.	
C126	TREFZ ET AL., "Long-term treatment of patients with mild and classical phenylketonuria by tetrahydrobiopterin," <i>Mol. Genet. Metab.</i> 2005 , <i>86</i> , S75-S80.	
C127	TREFZ ET AL., "Efficacy of sapropterin dihydrochloride in increasing phenylalanine tolerance in children with phenylketonuria: A phase III, randomized double-blind, placebo-controlled study," <i>J. Pediatr.</i> 2009 , <i>154</i> , 700-707.	
C128	TSAI ET AL., "Psychopharmacology in autism," <i>Psychosomatic Med.</i> 1999 , <i>61</i> , 651-665.	
C129	VASQUEZ-VIVAR ET AL., "Superoxide generation by endothelial nitric oxide synthase: The influence of cofactors," <i>Proc. Natl. Acad. Sci. USA</i> 1998 , <i>95</i> , 9220-9225.	
C130	VERMA ET AL., "Novel cardioprotective effects of tetrahydrobiopterin after anoxia and reoxygenation: Identifying cellular targets for pharmacologic manipulation," <i>J. Thoracic Cardiovasc. Surg.</i> 2002 , <i>123</i> , 1074-1083.	
C131	VILLASANA ET AL., "Neurological deterioration in adult phenylketonuria," <i>J. Inherit. Metab. Dis.</i> 1989 , <i>12</i> , 451-457.	
C132	WACHTEL, "Review of current practices in management of inherited disorders of amino acid metabolism in western Europe," <i>Human Nutr. Applied Nutr.</i> 1986 , <i>40A</i> , 61-69.	
C133	WALTER ET AL., "Inhalation of the nitric oxide synthase cofactor tetrahydrobiopterin in healthy volunteers," <i>Am. J. Respir. Crit. Care Med.</i> 1997 , <i>156</i> , 2006-2010.	
C134	WEGLAGE ET AL., "Tetrahydrobiopterin responsiveness in a large series of phenylketonuria patients," <i>J. Inherit. Metab. Dis.</i> 2002 , <i>25</i> , 321-322.	
C135	WEVER ET AL., "Tetrahydrobiopterin regulates superoxide and nitric oxide generation by recombinant endothelial nitric oxide synthase," <i>Biochem. Biophys. Res. Commun.</i> 1997 , <i>237</i> , 340-344.	
C136	YOSHIOKA ET AL., "Atypical phenylketonuria due to bipterin deficiency: Diagnosis by assay of an enzyme involved in the synthesis of sepiapterin from dihydroneopterin triphosphate," <i>Zoological Sci.</i> 1984 , <i>1</i> , 74-81.	
C137	ZURFLUH ET AL., "Pharmacokinetics of orally administered tetrahydrobiopterin in patients with phenylalanine hydroxylase deficiency," <i>J. Inherit. Metab. Dis.</i> 2006 , <i>29</i> , 725-731.	
C138	Letter from FDA to BioMarin Pharmaceutical regarding IND application no. 69,708 for tetrahydrobiopterin, dated September 27, 2004.	
C139	Letter from BioMarin Pharmaceutical to FDA in response to their comments in the September 27, 2004 letter regarding IND application no. 69,708 for tetrahydrobiopterin, dated October 19, 2004.	
C140	Office Action mailed 04/02/08, U.S. Application No. 10/990,316.	
C141	Office Action mailed 10/23/07, U.S. Application No. 10/990,316.	
C142	Office Action mailed 06/28/07, U.S. Application No. 10/990,316.	
C143	Office Action mailed 11/28/06, U.S. Application No. 10/990,316.	

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